

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELEWARE**

PFIZER INC., FOLDRX  
PHARMACEUTICALS, LLC, PF PRISM  
IMB B.V., WYETH LLC, and THE SCRIPPS  
RESEARCH INSTITUTE,

Plaintiffs

v.

AUROBINDO PHARMA LIMITED,

Defendant.

C.A. No. 23-01182 (UNA)

**DEFENDANT AUROBINDO'S ANSWER TO COMPLAINT**

Defendant Aurobindo Pharma Limited (“Aurobindo”), by its counsel, hereby responds to the allegations set forth in Plaintiffs Pfizer Inc.; FoldRx Pharmaceuticals, LLC; PF PRISM IMB B.V.; Wyeth LLC; and The Scripps Research Institute (referred collectively herein as “Plaintiffs”)’s Complaint against Defendant. The headings in Plaintiffs’ Complaint are copied herein for convenience only, and any allegations in such headings are denied.

1. Aurobindo admits that this action purports to arise under the United States Patent Laws, Title 35, United States Code, and under 28 U.S.C. § 2201 and 2202. Aurobindo admits that Plaintiffs purport to seek relief from alleged infringement by Aurobindo of U.S. Patent No. 7,214,696 (“the ’696 patent”) listed in the Orange Book for Plaintiffs’ Vyndaqel® (tafamidis meglumine) 20 mg capsules drug product.

2. Aurobindo admits that it notified Plaintiffs by letter dated October 4, 2023, that Aurobindo had filed ANDA No. 218617 (“Aurobindo’s ANDA”), which seeks FDA approval to

market its generic version of Plaintiffs' Vyndaqel<sup>®</sup> drug product prior to the expiration of the '696 patent. Aurobindo denies any remaining allegations in this paragraph.

### **PARTIES**

3. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and therefore denies them.

4. Aurobindo admits that FoldRx Pharmaceuticals is the holder of New Drug Application ("NDA") No. 211966. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint and therefore denies them.

5. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and therefore denies them.

6. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the Complaint and therefore denies them.

7. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 of the Complaint and therefore denies them.

8. Admitted.

9. Admitted that Aurobindo's ANDA seeks FDA approval to market Aurobindo's proposed ANDA product described therein prior to the expiration of the '696 patent. Aurobindo denies any remaining allegations of this paragraph.

### **JURISDICTION AND VENUE**

10. Paragraph 10 states a legal conclusion to which no response is required. Aurobindo will not contest subject matter jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

11. Paragraph 11 states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

12. Paragraph 12 states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

13. Paragraph 13 states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

14. Paragraph 14 states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

15. Paragraph 15 states a legal conclusion to which no response is required. Aurobindo will not contest venue for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

#### **FACTUAL BACKGROUND**

16. On information and belief, admitted.

17. On information and belief, admitted.

18. On information and belief, admitted.

19. Paragraph 19 states a legal conclusion to which no response is required. Admitted that Aurobindo's ANDA seeks FDA approval to market Aurobindo's proposed ANDA product described therein prior to the expiration of the '696 patent and that Vyndaqel® is a registered trademark of Pfizer under which it markets its 20 mg capsules. Aurobindo denies any remaining

allegations of this paragraph.

20. Admitted.

**COUNT I – INFRINGEMENT OF THE '696 PATENT**

21. Aurobindo incorporates each of the preceding paragraphs 1-20 as if fully set forth herein.

22. Aurobindo admits that the '696 patent bears the title “Compositions and Methods for Stabilizing Transthyretin and Inhibiting Transthyretin Misfolding” and an issue date of May 8, 2007. Aurobindo denies that the '696 patent was “duly and legally issued.” Aurobindo denies any remaining allegations in this paragraph.

23. Admitted.

24. Aurobindo admits that the '696 patent bears an assignee of “The Scripps Research Institute” on its face.

25. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint and therefore denies them.

26. Aurobindo admits that the '696 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) in connection with Vyndaqel®. Aurobindo denies all remaining allegations of this paragraph of the Complaint.

27. Aurobindo admits that claim 1 of the '696 bears the recited text. Aurobindo denies any remaining allegations in this paragraph.

28. Admitted that Aurobindo’s ANDA seeks FDA approval to market Aurobindo’s proposed ANDA product described therein prior to the expiration of the '696 patent.

29. Paragraph 29 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo admits that on October 4, 2023, it sent a Notice Letter to Plaintiffs pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic

Act and 21 C.F.R. § 314.95 and filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application (“ANDA”). Aurobindo denies any remaining allegations in this paragraph.

30. Denied.

31. Aurobindo admits that claim 1 of the '696 bears the recited text. Aurobindo denies any remaining allegations in this paragraph.

32. Aurobindo admits that in Aurobindo's Notice Letter it states that its proposed drug product contains 2-(3,5-dichlorophenyl)-1,3-benzoxazole-6-carboxylic acid mono (1-deoxy-1-methylamino-D-glucitol).

33. Admitted.

34. Aurobindo's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Aurobindo denies any remaining allegations of this paragraph.

35. Admitted that Aurobindo's ANDA seeks FDA approval to market Aurobindo's proposed ANDA product described therein. Aurobindo denies any remaining allegations of this paragraph.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Admitted that Aurobindo's ANDA seeks FDA approval to market Aurobindo's proposed ANDA product described therein prior to the expiration of the '696 patent. Aurobindo

denies any remaining allegations of this paragraph.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

## **COUNT II – DECLARATORY JUDGMENT**

45. Aurobindo incorporates each of the preceding paragraphs 1-44 as if fully set forth herein.

46. Aurobindo admits that there is a judiciable controversy between the parties as to Plaintiffs' allegation that Aurobindo infringes, induces infringement, and contributes to infringement by others of the '696 patent based on Aurobindo's proposed ANDA product, and/or to the validity of the '696 patent, suitable for resolution under the Declaratory Judgement Act. Aurobindo denies any remaining allegations in this paragraph.

47. Aurobindo admits that there is a judiciable controversy between the parties as to Aurobindo's liability for alleged infringement of the '696 patent based on Aurobindo's proposed ANDA product suitable for resolution under the Declaratory Judgement Act. Aurobindo denies any remaining allegations in this paragraph.

48. Denied.

## **RESPONSE TO REQUEST FOR RELIEF**

Aurobindo denies that Plaintiffs are entitled to any of the relief sought in their request for relief.

## **ADDITIONAL DEFENSES**

An allegation of any defense below is not an admission that Aurobindo bears the burden of proof or persuasion on any claim or issue.

**First Additional Defense- Non-Infringement**

49. Aurobindo has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claim of the '696 patent.

**Second Additional Defense – Invalidity or Unenforceability**

50. The claims of the '696 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and 116 and/or for double patenting.

**Third Additional Defense – Prosecution History Estoppel**

51. Plaintiffs' claims are barred, in whole or in part, by the doctrine of prosecution history estoppel. The claims of the '696 patent against Aurobindo are so limited as not to cover the manufacture, use, sale, offer for sale, or importation of the proposed ANDA products described in Aurobindo's ANDA due to the arguments, statements, representations and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the applications leading to issuance of the '696 patent.

**Fourth Additional Defense – Failure to State a Claim**

52. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

**RESERVATION OF ADDITIONAL DEFENSES**

Aurobindo reserves the right to assert such other defenses and damages, if such defenses or and damages are discovered during the course of this litigation.

**AUROBINDO'S PRAYER FOR RELIEF**

WHEREFORE, Aurobindo respectfully prays that this Court enter judgment in Aurobindo's favor and grant the following relief:

A. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for

relief contained therein;

B. A declaration that Aurobindo does not infringe the claims of the patent asserted against Aurobindo;

C. A declaration that the claims of the patent asserted against Aurobindo are invalid or unenforceable;

D. Award the costs of this action against Plaintiffs;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Aurobindo is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. A declaration that the effective date of any FDA approval of Aurobindo's proposed ANDA product shall not be stayed thirty months from the date of its Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Aurobindo of such further and other relief as this Court deems necessary, just, and proper.

Date: October 23, 2023

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